

REMARKS

Claims 1-6, 12, 15, 16, 43, 47, 48, 59-61, 140-146 and 174-176 are pending in this application. Claims 140-146 and 174-176 are withdrawn by the examiner. Claims 1-6, 12, 15, 16, 43, 47, 48, and 59-61 are currently under examination. Claims 6 and 48 are amended for clarity, as discussed herein. Therefore, no new matter is introduced. The Office Action is discussed below:

Obviousness Rejections:

On pages 2-5 of the Office Action, the examiner rejects Claims 1-4, 6, 12, 15, 16, and 59-61 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in view of Ashby *et al.* (PN 5989472).

On pages 5-6 of the Office Action, the examiner rejects Claims 43 and 48 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in view of Ashby *et al.* (PN 5989472) and Johnson (PN 4971761).

On page 6 of the Office Action, the examiner rejects Claim 5 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in view of Ashby *et al.* (PN 5989472) as applied to claim 1 above, and further in view of Kagiya *et al.* (PN 3894928).

On page 7 of the Office Action, the examiner also rejects Claim 5 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in view of Ashby *et al.* (PN 5989472) as applied to claim 1 above, and further in view of Patel (PN 4164458).

On pages 7-8 of the Office Action, the examiner rejects Claim 47 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in view of Ashby *et al.* (PN 5989472) and Johnson (PN 4971761) as applied to claim 43 above, and further in view of Patel (PN 4164458).

Applicants respectfully disagree on all of the above obviousness rejections, because the examiner has failed to establish a *prima facie* case of obviousness. Applicants submit:

"The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)...."

See MPEP § 2143.01 (III) at 2100-140 (Rev. 6, September 2007).

In this case, the specification discussed the Merrill *et al.*'s that provides methods for making irradiation of polymeric material (see specification, paragraph bridging pages 1 and 2, for example). In contrast, the invention provides new and improved methods for making and sterilizing medical implants containing crosslinked polyethylene that is in contact with another piece and forming interfaces. Since the results of irradiation of a medical implant having interfaces (such as a hybrid material) would not have been predictable to one of ordinary skill in the art, mere combination of irradiating polymeric material and adding a metal piece to the irradiated polymeric material would not make the claimed method obvious.

In addition, the applied references must teach or suggest all claim limitations. Applicants submit that the rejections do not meet this test and refer the examiner that:

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

See, MPEP § 2143.03 at 2100-142 (Rev. 6, September 2007).

According to the examiner, with regards to the independent claims 1, 43 and 59, Merrill teaches a method for forming a medical prosthesis for use in the body of ultra high molecular weight polyethylene (see abstract) in which a fabricated polyethylene article is irradiated using electron irradiation while at a

temperature above the melting temperature (referred to col. 2, lines 30-50) to reduce the free radicals in the article (refers to col. 11, lines 27-29). Merrill does not teach that the initial fabricated polyethylene article is compression molded to another piece. However, the examiner relies on Ashby for a method for forming prosthetic component in which a metal backing is molded to a polymeric substance in which the metallic grill is embedded within the plastic material (see abstract). Ashby describes compression molding the metallic piece to ultra high molecular weight polyethylene to provide a mechanical lock between the two parts (refers to col. 3, lines 5-13). Thus, the examiner believes that it would have been obvious to one of ordinary skill in the art to compression mold a ultra high molecular weight polyethylene article taught by Merrill (that is, compression molding a pre-irradiated polymeric material) to a wire mesh as taught by Ashby.

The examiner further relies on Ashby, Johnson, Kagiya, and/or Patel for limitations recited in the dependent claims.

Applicants point out that any combination of Merrill, Johnson, Kagiya, and/or Patel would not provide the claimed methods nor the resulting claimed medical implant containing crosslinked polyethylene that is in contact with another piece and forming interfaces. Because, none of the cited references teach or suggest:

- i) irradiating the hybrid material, or
- ii) heating of the hybrid material above the melting point of the crosslinked polyethylene.

Accordingly, any combination of the cited reference would not teach or suggest all claim limitations of the independent claims 1, 43 or 59. Thus, all independent claims and the claims depending therefrom are nonobvious over the cited references, as mandated in the MPEP, and as clarified above.

Applicants also submit that the combination of Merrill, Johnson, Kagiya, and/or Patel is nowhere supported by the references or in the common knowledge of the art. Accordingly, the rejection calls to mind the Federal Circuit

decision of *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998), where the court explained:

As this court stated, “virtually all [inventions] are combinations of old elements.” *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) (“Most, if not all, inventions are combinations and mostly of old elements”). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint to defeat the patentability of the claimed invention. Such an approach would be an “illogical and inappropriate process by which to determine patentability.” *Sensonics, Inc. v. Aerasonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996).

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventors and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

Thus, the rejection does not satisfy the strictures of the *Rouffet* decision. The references are not combinable without proscribed hindsight, that is, for example, the method steps of: i) irradiating the hybrid material or a medical implant having interfaces or ii) heating of the hybrid material or a medical implant having interfaces, as discussed above, would be based on the knowledge gleaned only from the instant disclosure. Such a reconstruction is clearly improper. *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).

See, MPEP § 2145 (X)-A at 2100-167 (Rev. 6, September 2007).

Therefore, withdrawal of the obviousness rejections is solicited.

Indefiniteness Rejection:

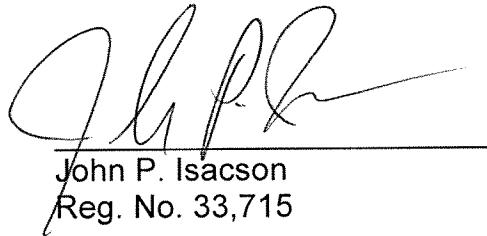
On page 8 of the Office Action, the examiner rejects claims 6 and 48 under 35 U.S.C. 112, second paragraph, allegedly as being indefinite for use of the phrase "or the like". In order to expedite the prosecution, applicants amend the claims by deleting the phrase, without prejudice or disclaimer.

Withdrawal of the rejection is therefore solicited.

REQUEST

Applicants submit that claims 1-6, 12, 15, 16, 43, 47, 48, and 59-61 are in condition for allowance and request consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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Date

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